

U.S.S.N.: 08/970,045

Filed: November 13, 1997

Amendment

determining the amount of HDL in the sample by  
adding to the sample monoclonal antibody molecules immunoreactive with high density  
lipoprotein and not cross-reactive with low density lipoprotein and determining the amount of  
high density lipoprotein; and  
determining the ratio of the amount of low density lipoprotein with the amount of high  
density lipoprotein.

40. A method for determining the relative ratio of VLDL to HDL in a biological  
sample comprising

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*cont*

determining the amount of VLDL in the sample by  
determining the amount of Apo C-III present in the VLDL in the sample by  
providing Pan B antibody which is characterized by an equal binding and high affinity for  
all Apo B-containing lipoproteins in human plasma,  
providing monoclonal antibody specifically immunoreactive with Apo C-III,  
contacting the antibody reactive with Apo C-III with the biological sample to form  
complexes between the antibody and the Apo C-III containing lipoprotein particles,  
contacting the Pan B antibody with the biological sample,  
*which are*  
separating the complexed antibody-lipoprotein particles from the biological sample,  
and  
determining the amount of Apo C-III associated with Apo B, which is the amount of Apo  
C-III present in VLDL in the sample; and  
determining the amount of HDL in the sample by

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determining the amount of Apo C-III present in the HDL in the sample by  
providing Apo A-I monoclonal antibody specifically immunoreactive specifically with  
Apo A-I,

providing monoclonal antibody specifically immunoreactive with Apo C-III,  
contacting the antibody reactive with Apo C-III with the biological sample to form  
complexes between the antibody and the Apo C-III containing lipoprotein particles,  
contacting the anti-Apo A-I antibody with the biological sample,  
separating the complexed antibody-lipoprotein particles from the biological sample,  
determining the amount of Apo C-III associated with Apo A-I, which is the amount of  
Apo C-III present in HDL in the sample, and

determining the ratio of Apo C-III present in VLDL in the sample and Apo C-III present  
in HDL in the sample which is the ratio of VLDL to HDL,

wherein the VLDL and HDL are measured in the same sample using immobilized  
antibodies or measured by immunoprecipitation in separate samples.

41. A method for determining the relative ratio of VLDL to HDL comprising  
determining the amount of VLDL in the sample by  
determining the amount of Apo E present in the VLDL in the sample by  
providing Pan B antibody which is characterized by an equal binding and high affinity for  
all Apo B-containing lipoproteins in human plasma,

providing monoclonal antibody which specifically binds to Apo E associated  
predominantly with VLDL,

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contacting the antibodies reactive with Apo E associated with VLDL with the biological sample to form complexes between the antibodies and Apo E containing particles,

contacting Pan B antibody with the biological sample, and

determining the amount of Apo E associated with Apo B which is the Apo E present predominantly in VLDL in the sample;

removing the complexed anti-Apo E:Pan B:Apo E containing particles by immobilization of the anti-Apo E antibodies or centrifugation of complexed particles;

and

determining the amount of HDL in the sample by

determining the amount of Apo E present in the HDL in the sample by

providing Apo A-I monoclonal antibody immunoreactive specifically with Apo A-I,

providing monoclonal antibody which binds to Apo E predominantly associated with

HDL,

contacting the antibodies reactive with Apo E to the biological sample to form complexes between the antibodies and Apo E containing particles,

contacting Pan B antibody with the biological sample,

determining the amount of Apo E associated with Apo A-I, which is the amount of Apo E present in HDL in the sample, and

determining the ratio of Apo E present in VLDL in the sample and Apo E present in HDL in the sample which is the ratio of VLDL to HDL.

42. A kit for determining the relative ratio of VLDL to HDL comprising

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Pan B antibody which is characterized by an equal binding and high affinity for all Apo B-containing lipoproteins in human plasma,

monoclonal antibody specifically immunoreactive with Apo C-III, and

monoclonal Apo A-I antibody specifically immunoreactive with Apo A-I.

43. The kit of claim 42 wherein the monoclonal or recombinant antibody molecules specifically immunoreactive with a single specific lipoprotein or apolipoprotein are selected from the group consisting of monoclonal antibodies, recombinant antibodies, and monoclonal antibody fragments that specifically bind to a stable, conformation independent epitope which is uninfluenced by the lipid content of the lipoprotein, apolipoprotein, or lipid associated with a specific lipoprotein.

44. A kit for determining the relative ratio of VLDL to HDL comprising

Pan B antibody which is characterized by an equal binding and high affinity for all Apo B-containing lipoproteins in human plasma,

monoclonal antibody which predominantly binds to Apo E associated with VLDL ,

monoclonal Apo A-I antibody specifically immunoreactive with Apo A-I, and

~~monoclonal antibody which predominantly binds to Apo E in HDL.~~

45. The kit of claim 44 wherein the monoclonal or recombinant antibody molecules specifically immunoreactive with a single specific lipoprotein or apolipoprotein are selected from the group consisting of monoclonal antibodies, recombinant antibodies, and monoclonal antibody fragments that specifically bind to a stable, conformation independent epitope which is uninfluenced by the lipid content of the lipoprotein, apolipoprotein, or lipid associated with a